

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of L-arginine on patient with refractory epilepsy

Protocol summary

Summary

Epilepsy is one of the world's most common non-transmissible disorders. Estimated 50 million persons are involved worldwide. Nearly 20-30% of these patients do not show desirable responses to antiepileptic drugs. In Kerman, 8/1000 populations need to use antiepileptic drugs. This study was aimed at investigating the effects of L-Arginine on the frequency and duration of attacks for refractory epileptic patients (two epileptic attacks every month after combination therapy by 2 or more antiepileptic drugs, simultaneously). Method: this study is double blind. Subsequent to obtaining informed consent, the patients were randomly divided into the two groups of intervention and control (21 subject to each group); the interventional group received L-arginine pills, twice the daily requirement, for three months, and the control group received pills containing starch, molded similar to L-arginine pills, as placebo for three months. Neither the patients nor the attending physician knew which patient received L-arginine or starch pills. The number and intensity (duration) of attacks were questioned from the patient or his/her carer and recorded in the specifically prepared questionnaire, once prior to taking the medicine or placebo, and again during treatment. After three months, the data, including seizure frequency was analyzed. The Adverse effects was also analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603078436N3**

Registration date: **2016-04-29, 1395/02/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-29, 1395/02/10

Registrant information

Name

Hossein Ali Ebrahimi

Name of organization / entity

Neurology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 34 1246 7500

Email address

hebrahimi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Neurology Research Center - Kerman University of Medical Sciences

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2017-01-18, 1395/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of L-arginine on patient with refractory epilepsy

Public title

Effect of L arginine on epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion : patients with epilepsy who have not responses to combination therapy(at least 2 attack per month) by antiepileptic drugs (at least 2 drugs); Exclusion: any disorders except epilepsy; Neurologic disorder except epilepsy; Pregnancy; hypersensitivity or adverse events

to L-arginine

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences

Street address
Jomhory Eslami Blvd

City
Kerman

Postal code

Approval date
2016-01-21, 1394/11/01

Ethics committee reference number
IR.kmu.REC.1394.515

Health conditions studied

1

Description of health condition studied
epilepsy

ICD-10 code
G40

ICD-10 code description

Primary outcomes

1

Description
Number of epileptic attacks

Timepoint

Duration of every attack in one month

Method of measurement
number

2

Description
severity of attacks

Timepoint
duration every attack

Method of measurement
number

Secondary outcomes

1

Description
non-tolerance

Timepoint
3 months

Method of measurement
report

Intervention groups

1

Description
L-arginine 2 size of daily need every day for three months

Category
Treatment - Drugs

2

Description
placebo(starch) 3-6 tablets every day for three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Medical Center + Neurologic clinic of Kerman
University of medical sciences

Full name of responsible person
Habibeh Mola Mohammadi

Street address
Kosar Blvd

City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neurology Research Center Kerman University of
Medical Sciences

Full name of responsible person

Elham Khadir

Street address

Kosar Blvd.

City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Neurology Research Center Kerman University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Research manager of Kerman university of medical
sciences

Full name of responsible person

Mahdi Ansari

Position

Pharmacy Professor

Other areas of specialty/work**Street address**

Somaeh cross way

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mansari@yahoo.co

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Neurology Research Center Kerman University of
Medical Sciences

Full name of responsible person

Hossein Ali Ebrahimi Meimand M.D

Position

Professor of Neurology

Other areas of specialty/work**Street address**

Neurology Research Center Kosar Blvd

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hebrahimi@kmu.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Afzali Pour Faculty

Full name of responsible person

Habibeh Mola Mohammadi

Position

Student

Other areas of specialty/work**Street address**

Afzali Pour Faculty - Kerman

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Kerman

Postal code**Phone**

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty